

REMARKS

In the above-identified Office Action, Examiner Snow made final his requirement for election of species, and made rejections of the claims he deemed to relate to an elected species. Reconsideration of the election requirement and of the claim rejections is respectfully requested.

The Election Requirement Should Be Withdrawn

On further consideration of the election requirement in light of the comments in the present Office Action, it is respectfully requested that the requirement be reconsidered and withdrawn. The present Office Action made it clear that the species election required by the Examiner concerned structure, while the claims at issue in this application are methods. That disconnect strongly favors withdrawal of the present election requirement.

37 C.F.R. 1.146 specifies that an election requirement may be made in an application that has a generic claim and claims to more than one “patentably distinct species embraced [by the generic claim].” The election must be to “a species of [the applicant’s] invention,” i.e. a part of the generic subject matter. In this case, the generic subject matter is a method for intervertebral stabilization having the steps as noted in the independent claims. Accordingly, a proper election requirement must identify patentably distinct species of that generic method.

However, the existing election requirement required a selection among “systems,” “positions” and “approaches,” none of which are particular species or types of actions or steps. “Systems” clearly suggest particular structure, and structure is not the generic claimed subject matter. “Positions” suggest either a relationship between structural parts or a result obtained from structure or method. The claimed subject matter is the method itself, not any particular structural feature or result. A claim to the result of a method is (or is akin to) a product-by-

process claim. “Approaches” also suggest a structural relationship between, in this case, devices and bodily tissue, rather than a particular patentably-distinct action. Respectfully, the election requirement does not focus on the generic method subject matter, but instead seeks to draw apparatus lines through the method claims.

As further noted below, this issue comes into focus with the Office Action’s questions as to whether certain elected apparatus meets the method claims. Respectfully, these questions miss the fact that the claims are directed to methods, not apparatus. It is submitted that further reconsideration of what is actually claimed will lead to the conclusion that the existing election requirement is not well-taken under Rule 146, and it causes confusion in the analysis of the cited references. Despite his assertion of its finality, Examiner Snow is respectfully requested to take another look at the election requirement and withdraw it.

Section 112, Paragraph 1 Rejections Should be Withdrawn

The Office Action rejected all claims as non-enabled, even though it only mentioned claims 1 and 19 in its brief comments concerning the rejection. “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.” *United States v. Electronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988), cited in MPEP 2164.01. “In order to make a rejection, the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention,” by providing a reasonable explanation as to why the scope of a claim is not adequately enabled. MPEP 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). “A specification disclosure which contains a teaching of the manner and process of making and

using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement . . . unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” MPEP 2164.04.

Respectfully, the Office Action does not meet its threshold burden, which is to provide some reasonable basis for doubting the objective truth of the application’s disclosure of the way to perform and use the claimed methods. No such basis has been given. Rather than providing a reasoned basis for doubt, the Office Action merely poses two question as to how the “elected embodiment” works. The Office Action does not use the phrase “undue experimentation,” much less attempt to analyze it. There is no evidence of record to suggest that any experimentation is needed to perform or use the claimed methods, and certainly no hint that any experimentation that might be needed could be called undue. By not following the standard and analysis set by law, the pending enablement rejection breaks down immediately.

Moreover, there is no objective, reasonable basis to question the presumptively accurate statements in the application. The specification uses substantially the same terms as the claims in describing the subject matter. And there is no requirement to spell out how disclosed subject matter works the way it does. The only requirement is to disclose material so that one of ordinary skill in the art can make and use the subject matter identified in the claims without undue experimentation. In other words, statements in this application are presumed to be true, there is no basis in any evidence of record to doubt the application, the language is presumptively enabling because of the terminology used in the specification, and the Office Action is not focused on the proper test for enablement. The statements and questions in the Office Action are simply not enough to sustain an enablement rejection of any of the claims.

The enablement rejection brings into sharp focus what appears to be a fundamental misunderstanding as to what is being claimed. The claims are drawn to methods, and yet the Office Action asks questions about how particular structures operate. Respectfully, while there are inevitably structural recitations in these (as in all) method claims, the election requirement that focuses on particular structures misses the method nature of the claims. Consider a claim to a method of tying shoes, and several different types of shoes are shown in the application. While the claim must at some point use the term “shoes,” that does not mean that its scope is limited to a particular pair, or that structural differences must be accounted for in determining whether an election requirement is necessary. Rather, a method claim is only restrictable if there are various methods or steps that are independent and distinct. It does not matter what the “expandable element” is in claim 1; what matters is whether there are several independent and distinct methods identified in different claims.

Respectfully, the Office Action’s focus on apparatus when method claims are under consideration is an indication that the proper subject matter is not being analyzed. This is another reason for withdrawing both the enablement rejection and the election requirement.

Section 112, Paragraph 1 Rejections Should be Withdrawn

The Office Action alleged that claims 18-20 and 34 were indefinite. This rejection should be withdrawn for at least the following reasons.

Initially, the rejection does not provide a sufficient *prima facie* case of indefiniteness, or a sufficient amount of information to assure a proper rebuttal. A claim is only indefinite if there is no way to give it an interpretation. *Exxon Res. and Eng’g Co. v. U.S.*, 265 F.3d 1371, 1375, 60 USPQ2d 1272, 1276 (Fed. Cir. 2001) (where “the meaning of the claim is discernible, even

though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear . . .”). The Office Action does not establish that any aspect of any of the rejected claims is incapable of interpretation.

As to claims 18 and 34, the Office Action merely stated that the phrase “degrading the load support element” is not understood. Unfortunately, that statement does not provide enough information as to a ground for rejection for a thorough discussion, particularly since the terms in the phrase are used in their normal sense. Further, the Office Action requests direction to the specification “for support,” which appears to refer to written description issues rather than indefiniteness. To the extent this ground for rejection is understood, it is noted that the “load support element” is properly identified in the claim, and indicates an element that supports a load. The straightforward term “degrading” applied to it indicates that the element degrades. One example of such a step is found at page 21, first paragraph of the specification.

As to claim 19, the Office Action merely asked what the last two lines mean. With due respect, these lines have their ordinary meaning in light of the specification (*see Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005)). Consequently, the second-last line indicates a removal of the recited expandable element from the recited expandable device, and the last line indicates maintenance of the recited height with the expandable device in its expanded form. In one example, an expandable element (e.g. items 55, 155 and others) can be removed from an expandable device (e.g. items 30, 130 and others), and that expandable device maintains a given height.

As to claim 20, respectfully Examiner Snow has misread the language. The expandable element (e.g. items 55, 155 and others) can be removed, but filler material may be placed in the

expanded expandable device (e.g. items 30, 130 and others), which remains in place. There is no conflict in claim 20, and it is capable of being interpreted.

To summarize, the allegation of indefiniteness should be withdrawn because it was not properly made, and because the claims are capable of a proper interpretation.

Section 102 Rejections over Bao Should be Withdrawn

Claims 1-2, 6-13, 16-25, 30, and 33-34 were alleged to be anticipated by the Bao reference (U.S. Patent No. 7,077,865). However, the analysis in the Office Action did not provide enough information to support such a rejection. The Office Action merely referred to Figure 14 of Bao, and then suggested that “applicant should consider all embodiments including figure 5,” items 162 in figure 12, and other undefined structures. It then copied the language of claim 1, adding parenthetical words or short comments to some but not all features. Finally, it listed five dependent claims, and for each provided only an instruction to “see” some part of the reference, but not explaining how the reference met those claims. The remaining dependent claims were given no analysis, with the Office Action concluding that they “are self-evident to one [of] skill in the art.”

This rejection does not meet the requirements of 37 C.F.R. §1.104(c), because the pertinence of each reference is not clearly explained, and each rejected claim is not specified with a particular part of the applied reference. The burden of establishing non-patentability is on the PTO, and respectfully this Office Action does not provide enough information concerning the Bao reference and its application to the present claims to meet that burden.

Nevertheless, in an effort to move prosecution along, an attempt will be made to respond to the rejection. In order to obtain a more complete analysis for further prosecution, claim 1 is

being amended as indicated above. Bao does not show or suggest a balloon for expanding an expandable element, which is then deflated and removed, and a separate motion preserving device being placed in a cavity of the expanded expandable device. The Office Action referred directly to Figure 14, but it and the text concerning it in Bao do not show or suggest expanding a balloon to expand an expandable device, deflating and removing the balloon, and placing a separate motion preserving device. Bao discloses using the same item 180 for both expansion and for curable polymer material. The Office Action's references to "mold" and to the compositions generally noted at column 24, line 17 are not understood.

Claims 2-18 are dependent from claim 1, and are allowable on that basis and/or on their own merit. As to the claims that were referred to in the Office Action, the following comments are offered. The Office Action appeared to refer to Bao's Figure 2 for "posterior approach," but Figure 2 shows only apparatus and does not have a reference to any body part. With respect to claim 13, the Office Action stated "see elements 13." However, no number 13 was found in any of Bao's drawings. The comment concerning claim 18 is not understood, since claim 18 recites that the removing load supporting elements step includes degrading the load supporting elements in situ. Further, the comment "the materials are biodegradeable" is not understood, since Bao does not recite that items 182 (which the Examiner considers to be an "expandable device") are made of biodegradable materials. In fact, it does not appear that the number 182 is used at all in the Bao text.

As to claim 19, the Office Action referred only to column 35, line 11 et seq. with the notation "teaching pre-distract by other elements can be done which are removed." While that comment is not fully understood, the text referred to appears to suggest a diagnostic "pre-distraction" of a "disc" prior to inserting any other device. It does not suggest at least the

recitation in claim 19 of removing an expandable element (e.g. a balloon) from an expanded expandable device, and maintaining a disc height with that expanded expandable device. The text at column 35, line 11 teaches at best only testing a “disc,” not expanding and leaving an expandable device, and Figure 14 does not show removing a balloon or other expandable element. Moreover, the present specification notes that distraction of a disc space prior to insertion of the collapsed expandable devices is not necessary (paragraphs 79, 89), which is the opposite of the disclosure relied on in the Office Action.

Additionally, the Office Action has not shown where in the Bao reference a motion preserving device separate from the expandable element is shown, and such a disclosure has not been found in the reference. Examples of a motion preserving device are given in paragraph 74 of the present specification, and are associated with the examples of expanded device 30, expandable element 55 and other parts of Figure 1. Elastic cores and/or motion preserving devices are disclosed as a part of many embodiments (see *inter alia* paragraph 11).

For at least these reasons, independent claims 1 and 19 have not been shown to be anticipated by Bao.

Section 102 Rejections over Teitelbaum Should be Withdrawn

Claims 1-2, 6-27, 30, and 33-34 were rejected as allegedly anticipated by U.S. Patent No. 6,582,467 to Teitelbaum. This rejection also does not meet the requirements of 37 C.F.R. §1.104(c), because there is no discussion at all of how the reference purports to meet any of the claim language. Even more so than with respect to Bao, the pertinence of Teitelbaum is not clearly explained, and each rejected claim is not specified with a particular part of Teitelbaum. The burden of establishing non-patentability is on the PTO, and respectfully this Office Action

does not provide enough information concerning Teitelbaum and its application to the present claims to meet that burden.

Without any discussion of Teitelbaum in the Office Action, it is respectfully submitted that no substantial response is required or possible. It is noted that the Teitelbaum reference appears to disclose a fusion device having a rigid exterior for promotion of fusion between vertebrae. A rigid connection for fusion enables stable bone to grow between the vertebrae without the interference and potential damage of the vertebrae moving with respect to each other. Claim 1 of the present application, however, recites a motion preserving device, which of course does not provide that rigid connection but instead allows movement between vertebrae. Additionally, the step of accessing a collapsed disc space was not found in Teitelbaum, which instead describes removal of nuclear material, apparently leaving annular material to maintain the space, and inserting a cage.

Section 102 or 103 Rejections over Bao Should be Withdrawn

The Office Action further alleged that claims 14-15 and 26-27 are either anticipated by or obvious over the Bao reference. The alternative quality of this rejection is not understood, since either the reference has all of the elements, or it does not, and it is respectfully requested that one basis or the other be relied on.

Claim 14 recites that the expanded expandable device has a first height at a distal end and a second height at a proximal end, and one height is greater than the other. The Office Action does not cite any part of Bao as showing that feature, and Applicant's attorney has not found such disclosure either. The Office Action claimed that Bao teaches a prosthesis that "restores the desired anatomy and function of the disc" to a "natural state." The Examiner is respectfully

requested to provide a particular citation in Bao for that disclosure, since Applicant's attorney did not find it. The occurrences of the word "natural" in the specification referred to existing tissue or the source of certain items ("natural fibrous tissue" or "natural" reinforcing materials). Even if the Office Action's claim is correct, such a general statement does not demonstrate a difference in height between the ends of an intervertebral implant. It further asserted that "some adjacent vertebrae naturally have a greater anterior height." However, the height of vertebrae is not at issue, since the claims describe a difference in the height of the ends of an expandable device. As to section 103, the Office Action again mentioned vertebral height, which is immaterial to claims 15-16 and 26-27, and noted another reference to Erickson. While the Office Action asserted that obviousness is based on Bao alone, its analysis appears to include information from another reference. Accordingly, the rejection of claims 15-16 and 26-27 as either anticipated by or obvious over Bao alone should be withdrawn.

New Claims

New claim 72 is specifically directed to particular steps in placing a motion preserving device. It is fully supported by the specification, including paragraphs 74 and 79-80, among others. No new matter has been added. Neither of the references disclose expanding an expandable device with a first expandable element, deflating and removing it, and then placing a motion preserving device which may be another expandable element.

Neither Bao nor Teitelbaum appear to speak to the reformation or correction of scoliosis by expanding an expandable device on one side of the spinal midline. Claim 16 speaks specifically to the correction of a scoliotic curvature, and new claim 73 expands on that subject matter. These new claims are fully supported by the application, including by paragraphs 107-

109, among others, which specifically states that all embodiments of the expandable device would be useful with the described method. No new matter has been added.

Cancellation of Claims

Claims 35-71, directed to apparatus, have been cancelled without prejudice to reconsideration in this or a continuing application. This is being done to move this application more quickly toward allowance, and is not to concede any basis for restriction of those claims from this application.

Conclusion

It should be understood that the above remarks are not intended to provide an exhaustive basis for patentability or concede the basis for the rejections in the Office Action but are simply provided to address the rejections made in the Office Action in the most expedient fashion. Applicant reserves the right to later contest positions taken in the Office Action that are not specifically addressed herein. Further, no limitation of the claims is intended by any of the remarks herein. The claims are intended to have the full scope to which their language entitles them.

In conclusion, reconsideration and withdrawal of the rejections of the claims based on the remarks presented is respectfully requested. The undersigned attorney invites Examiner Snow to call to discuss any further issues that may remain.

Respectfully submitted,

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